



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 19 2011

Re: PRISTIQ
Patent Nos. 6,673,838 and 7,291,347
Docket Nos. FDA-2009-E-0084
FDA-2009-E-0086

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the patent term extension applications for U.S. Patent Nos. 6,673,838 and 7,291,347 filed by Wyeth under 35 U.S.C. § 156. The patents claim PRISTIQ (desvenlafaxine succinate), new drug application (NDA) 21-966.

In the August 31, 2010, and September 2, 2010, issues of the *Federal Register* (75 Fed. Reg. 53314 and 53969, respectively), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notices provided that on or before February 28, 2011,¹ 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to these notices has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

¹ In the May 16, 2011, *Federal Register* (76 Fed. Reg. 28235), the comment period was reopened until June 15, 2011, to allow interested parties to submit comments or petitions to docket number FDA-2009-E-0086 (PRISTIQ, Patent No. 7,291,347), because that docket number had been inadvertently omitted in the August and September 2010 *Federal Registers*.

cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth St., NW
Washington, DC 20004